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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,825	03/30/2004	Theoharis C. Theoharides	51275/147	3056

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DR. MELVIN BLECHER
4329 VAN NESS ST., NW
WASHINGTON, DC 20016

EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,825	THEOHARIDES, THEOHARIS C.	
	Examiner	Art Unit	
	Sheridan R. MacAuley	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-49* is/are pending in the application.

4a) Of the above claim(s) *40-44 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1609, Examiner MacAuley.

A preliminary amendment was received and entered on March 30, 2004.

Claims 1-39 were cancelled.

Claims 40-49 are pending.

Election/Restrictions

1. Applicant's election with traverse of the Group III invention, claims 45-48, in the reply filed on January 17, 2007 is acknowledged. The traversal is on the ground(s) that product and process of making claims can be examined together. This is not found persuasive because restriction between product and process claims is proper. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. See MPEP § 804.01. Any attempt to rejoin the process claims prior to an action where the product claims are found allowable will be unresponsive because the process claims are drawn to a nonelected invention.

2. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 40-44 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

4. Claims 45-48 are examined on the merits.

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

6. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/056,707, filed April 4, 1998, Application No. 09/771,669 filed January 30, 2001, and Application No. PCT/US02/00476, filed January 3, 2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). **For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications.** If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the

application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

7. If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or

an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

8. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

9. The disclosure of the prior-filed applications, Application No. 09/056,707, filed April 4, 1998, Application No. 09/771,669 filed January 30, 2001, and Application No. PCT/US02/00476, filed January 3, 2002, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The applications to which the instant application claims priority do not disclose a medical device coated with an anti-inflammatory compound.

Response to Amendment

The amendment to the claims filed on March 30, 2004 does not comply with the requirements of 37 CFR 1.121(c) because amendments to the specifications and to the claims are not on separate pages and the amendments to the claim were not in the correct format. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a

clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 45-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 45 recites a medical device for implantation in or upon tissues coated with an anti-inflammatory composition. It is unclear whether the device or the tissues are coated with the composition.

13. The term "highly" in claim 46 is a relative term, which renders the claim indefinite. The term "highly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 47 and 48 are indefinite insofar as they depend from claims 45 and 46.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claim 45 is rejected under 35 U.S.C. 102(b) as being anticipated by Shikani et al. (US Pat. 5,762,638, 1998). Claim 45 recites a medical device for implantation in or upon tissues coated with an anti-inflammatory composition.

16. Shikani et al. teach an implantable medical device coated with an anti-inflammatory composition (col. 10, lines 1-25). Therefore, claim 45 of the instant application is anticipated by Shikani et al.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 45-48 are rejected under 35 U.S.C. 103(a) as being obvious over Morrison (GB 2098506 A, 1982) and Hwang et al. (US Pat. 5,948,814, 1999) in view of Theoharides (US Pub. 20020176902). Claim 45 recites a medical device for implantation in or upon tissues coated with an anti-inflammatory composition. Claim 46 further limits claim 45 by reciting that the anti-inflammatory composition comprises a non-bovine, highly sulfated proteoglycan and a flavonoid compound. Claims 47 and 48 further limit claim 46 by reciting that the proteoglycan is chondroitin sulfate, and that the flavonoid compound is quercetin, myricetin or genistein, respectively.

20. Please note that applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120, as discussed in paragraphs 8 and 9 above. Briefly, the disclosure of the prior-filed applications (US Application 09/056,707, US Application 09/771,669 and PCT/US02/00476) fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The applications to which the instant application claims priority do not disclose a medical device coated with an anti-inflammatory composition.

21. Morrison teaches an implantable medical device coated with a composition comprising non-bovine highly sulfated proteoglycan (specifically, chondroitin sulfate from shark cartilage; p. 3, lines 55 and 69-74). Morrison does not teach that the coating comprises a flavonoid compound.

22. Hwang et al. teaches an implantable medical device comprising a flavonoid compound (specifically, genistein; col 7, lines 39-47). Although Hwang et al. do not teach that the flavonoid compound is coating the implantable medical device, it would be inherent to the construction of the device that the flavonoid compound would be present on or coating a surface. Hwang et al. do not teach an implantable medical device comprising a non-bovine highly sulfated proteoglycan.

23. Theoharides teaches an anti-inflammatory composition comprising a heavily sulfated, non-bovine proteoglycan (specifically, chondroitin sulfate) and a flavonoid compound (including quercetin, myricetin and genistein; see claims 1 and 5).

24. At the time of the invention, implantable medical devices coated with chondroitin sulfate and flavonoid compounds (specifically, genestein) were known in the art, as taught by Morrison and Hwang et al. It was also known that chondroitin sulfate and flavonoid compounds (including quercetin, myricetin and genistein) could be combined in an anti-inflammatory composition, as taught by Theoharides. The motivation to combine these teachings by producing a medical device coated with chondroitin sulfate and genistein is provided by Theoharides, who teaches that the two compositions can be put together to form an anti-inflammatory composition, and by Morrison and Hwang et al., who teach that both compounds are suitable for use in implanted medical devices. It would therefore have been obvious to one skilled in the art to the teachings to produce the claimed medical device coated with an anti-inflammatory composition comprising chondroitin sulfate and genestein.

25. One skilled in the art would have a reasonable expectation of success combining the teachings discussed above because medical devices coated with both chondroitin sulfate and genestein were known in the art at the time of the invention, as taught by Morrison and Hwang et al, and chondroitin sulfate and genestein were known in the art to be compatible ingredients in an anti-inflammatory composition, as taught by Theoharides. Therefore, one of ordinary skill in the art would have been able to combine the teachings discussed above by developing a medical device coated with an anti-inflammatory composition comprising chondroitin sulfate and genestein with a reasonable expectation of success.

26. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

27. The following references are cited as of interest because their teachings are similar to those discussed above and they serve to reinforce the conclusions made in this action:

- Yannas et al. (US Pat. 4,060,081). Reference discusses a synthetic skin coated with a composition comprising chondroitin sulfate.
- Ellingsen et al. (US Pub. 2002/0111694 A1). Reference discusses medical prosthetic devices and implants comprising chondroitin sulfate.
- de Juan (US Pat. 5,980,929, 1999). Reference discusses an implantable medical device comprising genestein.

- Young et al. (US Pub. 2003/0054357). Reference discusses implantable medical devices coated with quercetin.
- Sugimoto (US Pub. 2002/0035395). Reference discusses an implantable medical device comprising flavonoids.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DANIEL M. SULLIVAN, PH.D.
PRIMARY EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

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